JUL 15 2004

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

On behalf of Waiora International, Inc., 1829 Corporate Drive, Boynton Beach, Florida, 33426, the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6). The certification required by 21 C.F.R. § 101.93(a)(3) is attached.

Brand Name: Healthy Aging Formula

## **Dietary Ingredients:**

Supplement Facts

Serving Size: 2 caplets Servings Per Container: 60

Amount Per Serving % Daily Value

Calories 5

Protein 0g 2%\*

Calcium 22mg 2%

Proprietary Y.E. Blend/Complex 1100mg†

bioactive hyperimmune milk protein concentrate

3ß-acetoxyandrost-5-ene-7, 17-dione

\* Percent Daily Values are based on a 2000 calorie diet

† Daily Value not established.

Other ingredients: Dicalcium phosphate, xylitol, sodium starch glycolate, magnesium stearate, silicon dioxide. Contains milk proteins, 90% Lactose Free.

975 0162

LE7

14358

88972

## **Statements of Nutritional Support:**

Specially formulated to promote healthy joints, accelerate weight loss when dieting and exercising, and support immune and cardiovascular function.\*

Waiora's Healthy Aging Formula uses a proprietary blend of ingredients (including 3\beta-acetoxyandrost-5-ene-7, 17-dione and bioactive hyperimmune milk protein concentrate) to help reduce the effects of aging by naturally replenishing key compounds that decline with age.\* When combined with your daily nutritional regimen, including a sensible diet and exercise program, Healthy Aging Formula can help promote proper joint function and mobility, enhance a weight control program and maintain lean muscle mass, support a healthy immune system, and promote healthy heart and cardiovascular system.\*

Waiora International, Inc.

By: Stanley J. Cherelstein

President & CEO

Attachment - Certification

[NOTE: An original and two copies of the notification and certification must be submitted to FDA.]

## 21 C.F.R. § 101.93(a)(3) Certification

I certify that the information contained in the preceding section 403(r)(6) notice for *Healthy Aging Formula* is complete and accurate and that *Waiora International, Inc.* has substantiation that the statements are truthful and not misleading.

By: Stanley J. Cherelstein

President & CEO

June 10, 2004

[NOTE: This certification must be signed by an individual who can certify the accuracy of the information presented in the notification.]